

From: Stephen Chadwick
Sent: Wednesday, May 02, 2001 12:32 PM
To: tituss@cder.fda.gov
Subject: Antihistamines

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Dear Ms. Titus:

I have been a private practice otolaryngologist who practices rhinology and related otolaryngic allergy for over 20 years. As such I have had the opportunity to experience the downsides as well as any benefit of first generation antihistamines going over the counter. I also have a clinical position with the Southern Illinois School of Medicine and actively teach physicians-in-training as well as other practicing physicians.

I would highly and strongly recommend that the FDA not let second generation antihistamines go over-the-counter. Today's patient is much more aware and educated with regard to illness and medical conditions thanks to our era of information-plenty. Unfortunately this also put him in a position of making medication decisions without enough information, qualified or otherwise, about his condition. I have seen serious conditions, such as intranasal malignancies misdiagnosed by the patient as an allergy-sinus problem go undiscovered, delaying appropriate treatment, because of treating the symptoms with over-the-counter antihistamines without proper physician input. There are, of course, many other conditions of less lethal consequence, but still of significant potential of morbidity that fall in to this same line of reasoning.

We are now in a period of using combinations of drugs to treat sinus and allergy related matters. The decision of adding other medication such as antihistamines should rest with the physician or other qualified health-care worker. Side effects and morbidity will occur without this professional input. Of course drug-drug interactions with other drugs the patient is on at the time for other reasons is another issue.

The above comments are an important few that are not financially driven. It is very upsetting to me that the insurer's petition is financially driven and will not only put patients at risk for bad outcomes, but will also push a big financial burden to the patient, including those on Medicare and Medicaid.

Thank you for your time.

Stephen Chadwick, MD

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